

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
93-R-0368

CUSTOMER NO.
1297

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

FIBROGEN, INC.
225 GATEWAY BLVD
SAN FRANCISCO, CA 94080

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS/sites

(b)(2)High, (b)(7)(F)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits				18	18
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

(b)(6),(b)(7)(c)

(b)(6),(b)(7)(c)

11/30/2007

1. Registration Number: 93-R-0368 / 1297

2/3. Species (common name) & Number of animals used in this study:

Rabbits (18)

4. Explain the procedure producing pain and/or distress.

The purpose of this protocol is to determine potential toxicity of new compounds for clinical use in fibrotic diseases, anemia and cytoprotection (e.g., myocardial infarction and stroke) to determine the safety profile, i.e., potential mortality rate, clinical observations and effects on clinical chemistry, hematology and macroscopic/microscopic pathology. Safety profiles are determined in animals prior to administration of new compounds to humans. Therefore, toxicity testing is performed to determine the toxic dose, the organs that are most affected by the compound and whether these toxic effects are reversible over time. There is no suitable in vitro substitute for the potential pathophysiological relationship observed in vivo. Animal models have been used historically and reliably to predict the clinical safety profile. Further, regulatory agencies require determination of safety profiles in animals prior to testing new compounds in humans. Typically, at least one rodent and one non-rodent species must be used to satisfy regulatory agency testing requirements. The rabbit will serve as the non-rodent species in this protocol. Administration of new chemical entities may induce adverse clinical outcomes in these studies. The purpose of these studies is to evaluate toxicity and therefore, the use of additional agents may confound results.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Administration of new chemical entities may induce adverse clinical outcomes in these studies. The purpose of these studies is to evaluate toxicity and therefore, the use of additional agents may confound results. Safety assessment in animals is required by regulatory agencies. The minimum number of animals will be used to achieve an adequate assessment. For example, dose-range finding studies may be determined using a group size of four animals which will be humanely euthanized at or before the end of the working/dosing day using methods and humane endpoints described for acute and repeat dose studies described above. Any moribund animal will be humanely euthanized. There is no suitable in vitro alternative with which to reliably determine the safety profile. A literature search performed on April 18, 2007 (Pubmed and Medline) from 1970 to 2007 using the key words in combination(s): in vitro, alternative, rabbit, toxicity, toxicology, in vivo, ICH revealed no viable alternatives.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: ICH, S4, S5-Detection of Toxicity to Reproduction CFR:
- Initial Dose Range Finding Assessment - Single Dose
Toxicity Test - Duration of Chronic Toxicity Testing in
Animals(Rodent and Non-Rodent)

Approval Status:

Approved/Disapproved By:

Date:

Disapproved Reason: